



BioSante and LibiGel® Market Overview

January 2011

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For BioSante, particular uncertainties and risks include, among others, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; the marketing success of BioSante's licensees or sublicensees; the success of clinical testing; and BioSante's need for and ability to obtain additional financing.

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BioSante Overview

Company Information

Corporate Background

BioSante is a specialty pharmaceutical company focused on developing and commercializing products for female sexual health and oncology.

Business Overview

BioSante is focused on the *development and commercialization* of products for female sexual health, menopause, contraception, male hypogonadism, and oncology.

Clinical Portfolio









BioSante currently has *promising late-stage assets* for the treatment of female sexual dysfunction, contraception, and male hypogonadism, as well as a portfolio of cancer vaccines.

Management Team

BioSante has a strong management team with *extensive product development* and public company experience.

BioSante's Product Portfolio

BioSante has several late-stage assets indicated for female and male sexual health, as well as a portfolio of cancer vaccines.

Product	Indication	Preclinical	Early Human Clinical	Late Human Clinical	FDA Approval	Marketing Rights
Elestrin™ (Estradiol gel)	Menopausal symptoms	Marketed				 (US rights)  (China, and various other countries)
LibiGel® (Testosterone gel)	Hypoactive Sexual Desire Disorder (HSDD)	Phase III under an SPA				 (US, China, and various other countries)
The Pill-Plus™	Contraception + Androgen	Phase II				 (US, Oral use)  (US, TD use)
Bio-T-Gel™	Male Hypogonadism	FDA submission < 6 months				 (US)  (Ex-US)
Cancer Vaccines	Various Cancers	Phase II				 (Global)

LibiGel[®] Overview

LibiGel Opportunity—Overview

LibiGel, a valuable asset with a well-defined regulatory pathway, is anticipated to launch in 2012.

Asset Summary

1

High Unmet Need

No FDA-approved agents exist for female sexual dysfunction (FSD). Current off-label prescribing is estimated at 4.1M prescriptions per year.

2

Differentiated Asset With Favorable Profile

Phase II results showed remarkable (238%) improvement in satisfying sexual events and a safety profile similar to placebo. Additionally, blinded ongoing results show lower rates of serious CV events than expected.

3

First to Market

LibiGel is anticipated to be the first product FDA-approved in the US for the treatment of FSD or related conditions.

4

Favorable Response From Prescribers

Interviewed physicians were very bullish on LibiGel. They were receptive to the product profile and suggested that this would replace almost all of the current off-label prescribing for FSD.

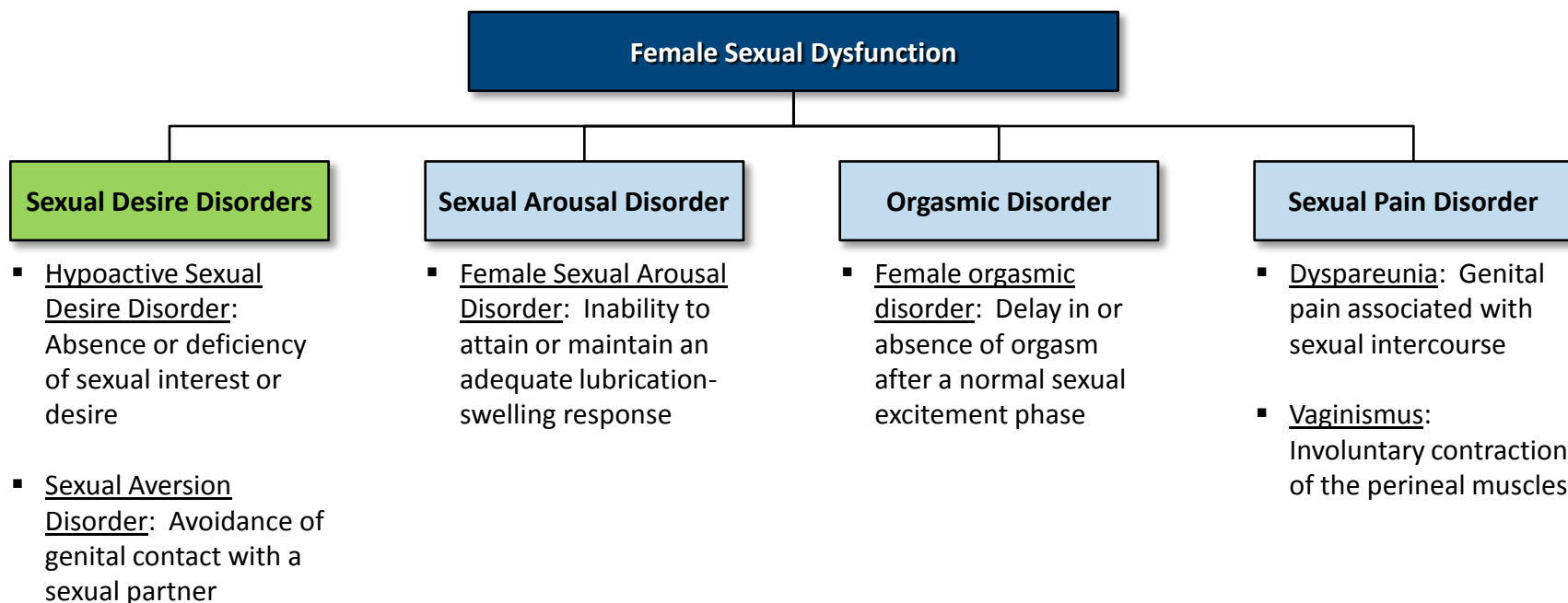
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Large Market Potential

LibiGel is anticipated to launch in 2012
—with potential to be a blockbuster asset.

High Unmet Need—Large Patient Population

Female sexual dysfunction includes a range of conditions that include hypoactive sexual desire disorder (HSDD).



Approximately 40 million women in the US suffer from Female Sexual Dysfunction.

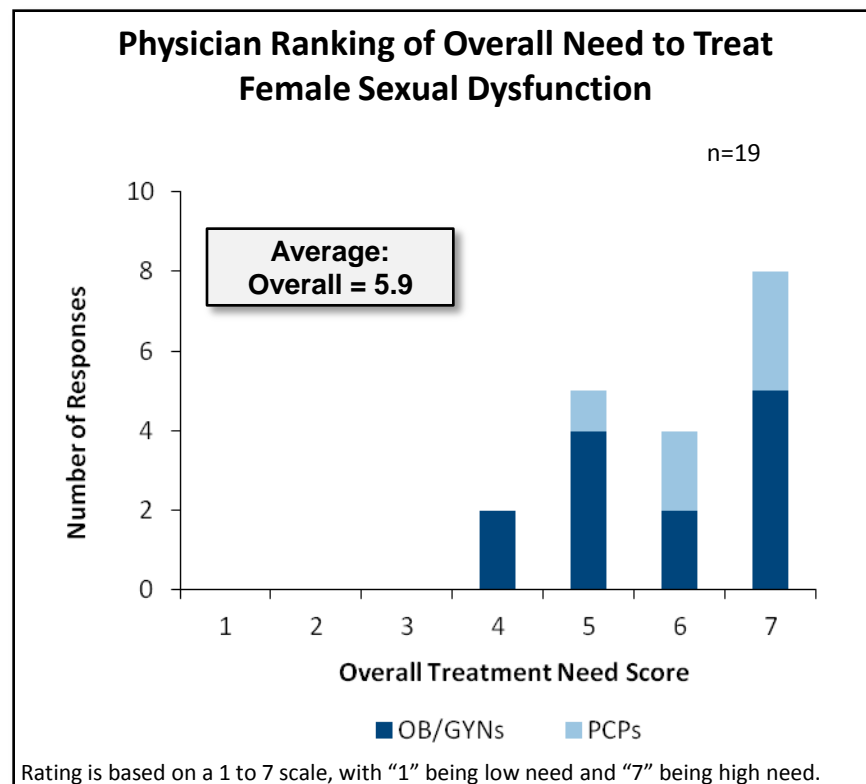
Sources: Elder J and Braver Y. Female Sexual Dysfunction. Cleveland Clinic. Available at <http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/womens-health/female-sexual-dysfunction/>. Accessed February 2010; Diagnostic and Statistical Manual of Mental Disorders 4th edition, text revision; West S et al. Prevalence of low sexual desire and hypoactive sexual desire disorder in a nationally representative sample of US women. *Arch Internal Medicine*. July 14, 2008; Volume 168; MayoClinic.com. Low Sex Drive in Women. Available at: <http://www.mayoclinic.com/health/low-sex-drive-in-women/DS01043>. Accessed June 2010; Laumann EO, Paik A, Rosen RC. Sexual Dysfunction in the United States. *JAMA*. 1999 Feb 10;281(6):537-44.

High Unmet Need—Desire for Pharmaceutical Treatment Options

Physicians are looking for pharmaceutical treatment options for FSD even though no therapeutic options currently exist.

- Physicians responded that overall ***awareness of FSD is increasing*** due to
 - Approved products for male sexual dysfunction
 - Less cultural stigma
 - Aging US patient population
- Overall, the physician panel indicated a ***high unmet medical need***, with an even higher perceived medical need in the primary care community.

“The need to treat is very high because it’s a very important aspect of a patient’s life.” – Physician

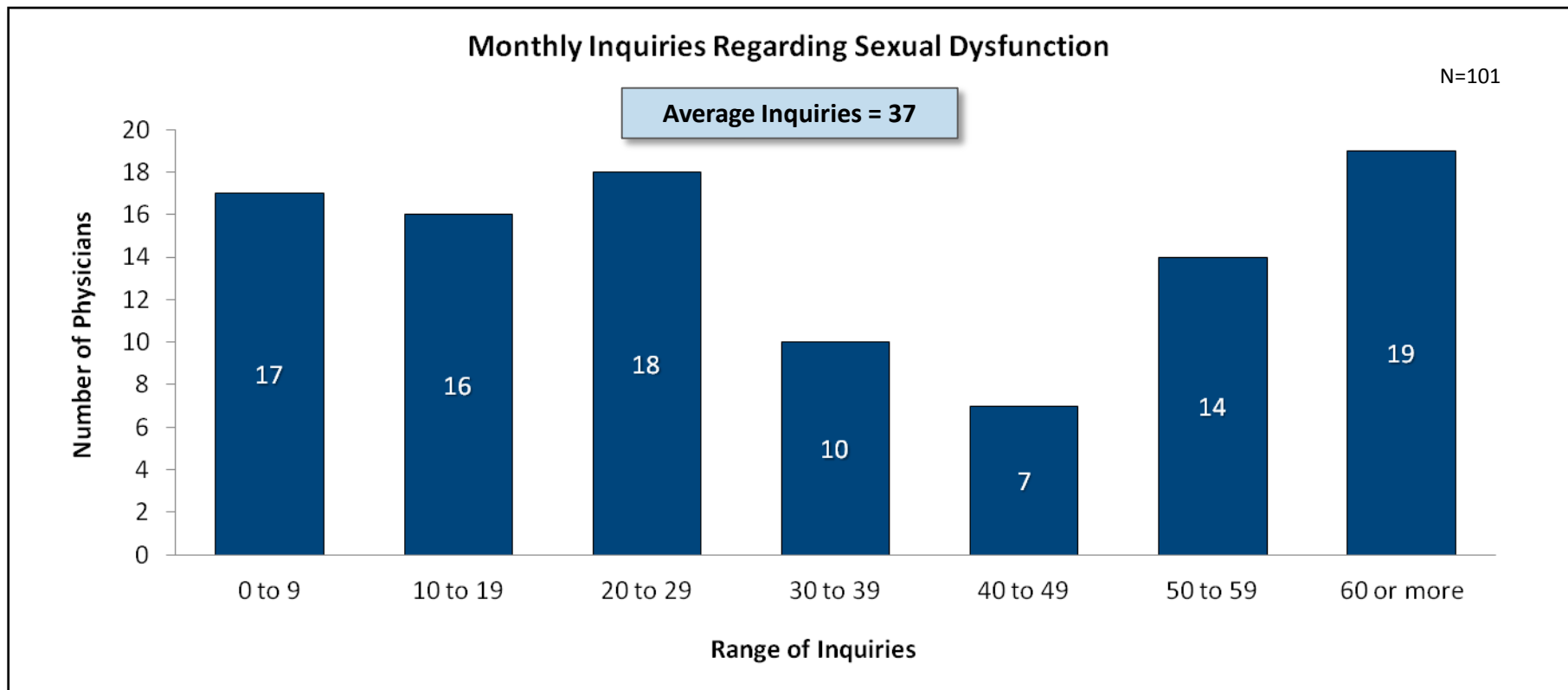


The majority of physicians interviewed believed that female sexual dysfunction is an important and legitimate disorder requiring treatment.

Source: Results of 20 interviews (15 OB-GYN, 5 PCP) conducted by Campbell Alliance in February and March 2010. Note: One physician did not respond to this question.

High Unmet Need—Patient Inquiries

Market research showed that sexual dysfunction is *one of the most common complaints* in gynecologist offices.

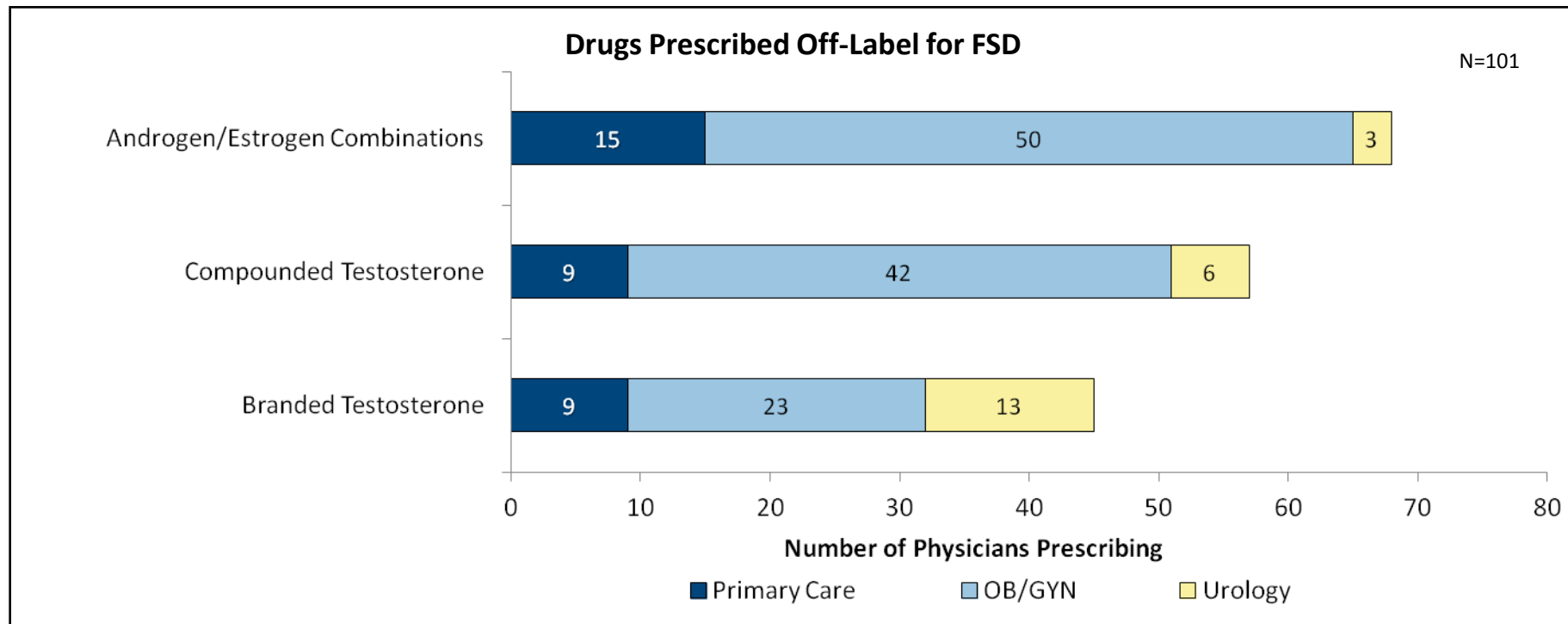


The frequency of inquiries related to female sexual dysfunction potentially could increase with a first-approved drug like LibiGel on the market.

Source: Results of Campbell Alliance primary research surveys/interviews with 101 physicians. March 2010 to April 2010.

High Unmet Need—Current Hormone Replacement Therapies

Although there are currently no medications approved by the FDA for female sexual dysfunction, the significant *majority of physicians reported prescribing androgen and androgen-estrogen combinations off-label* for their FSD patients.



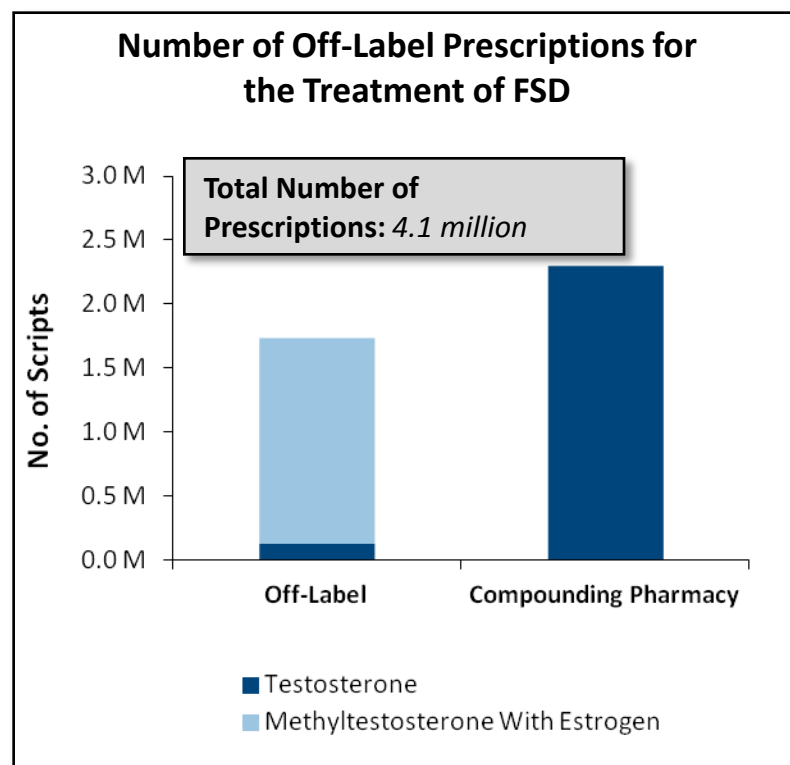
A significant majority of physicians are prescribing androgen, and androgen-estrogen product combinations despite the lack of approved products within this space.

Source: Results of Campbell Alliance primary research surveys/interviews with 101 physicians. March 2010 to April 2010.

High Unmet Need—Prescription Rates for FSD Therapies

Testosterone therapies are prescribed off-label to alleviate the symptoms of FSD, but among these marketed products, there is a lack of clinical studies and consistent, precise dosing in women with FSD.

Drug Product	Sample Products	Benefits	Limitations/ Side Effects
Testosterone	<ul style="list-style-type: none"> Androgel Testim 	Potentially increases sexual desire by raising levels of testosterone	<ul style="list-style-type: none"> No data indicating appropriate dose (poor dosing control)
Methyl Testosterone With Estrogen	<ul style="list-style-type: none"> Estratest EEMT Essian H.S. 		<ul style="list-style-type: none"> Limited efficacy data available Potential androgenic side effects Potential liver toxicity



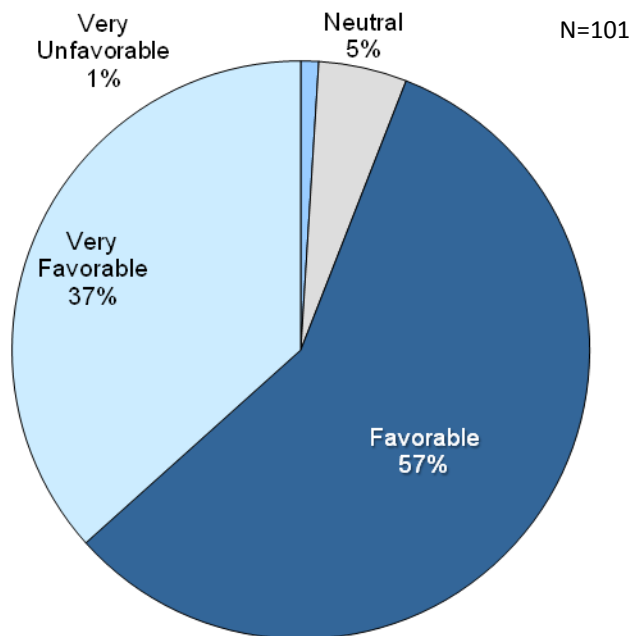
Among available testosterone products, approximately 1.8 million prescriptions are filled off-label annually for FSD. Additionally, research indicates 2.3 million prescriptions for testosterone are filled at compounding pharmacies.

Sources: Elder J, Braver Y. Female Sexual Dysfunction. Cleveland Clinic. Available at <http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/womens-health/female-sexual-dysfunction/>. Accessed February 2010; IMS HEALTH Confidential and Proprietary; Source: IMS Health Incorporated, National Sales Perspectives; Results of Campbell Alliance primary research surveys/interviews with 101 physicians. March 2010 to April 2010.

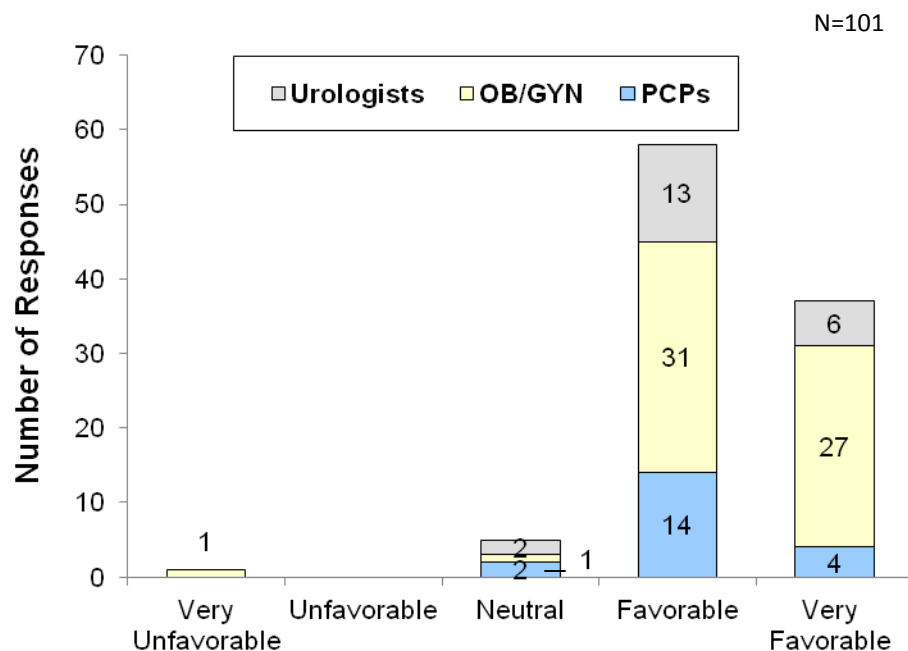
Quantitative Market Research—Physician Reaction to LibiGel

Additionally, quantitative market research was conducted with 101 physicians. *94% of physicians were either favorably or very favorably inclined* towards the profile of LibiGel.

Product Ratings Overall



Product Rating by Physician Type



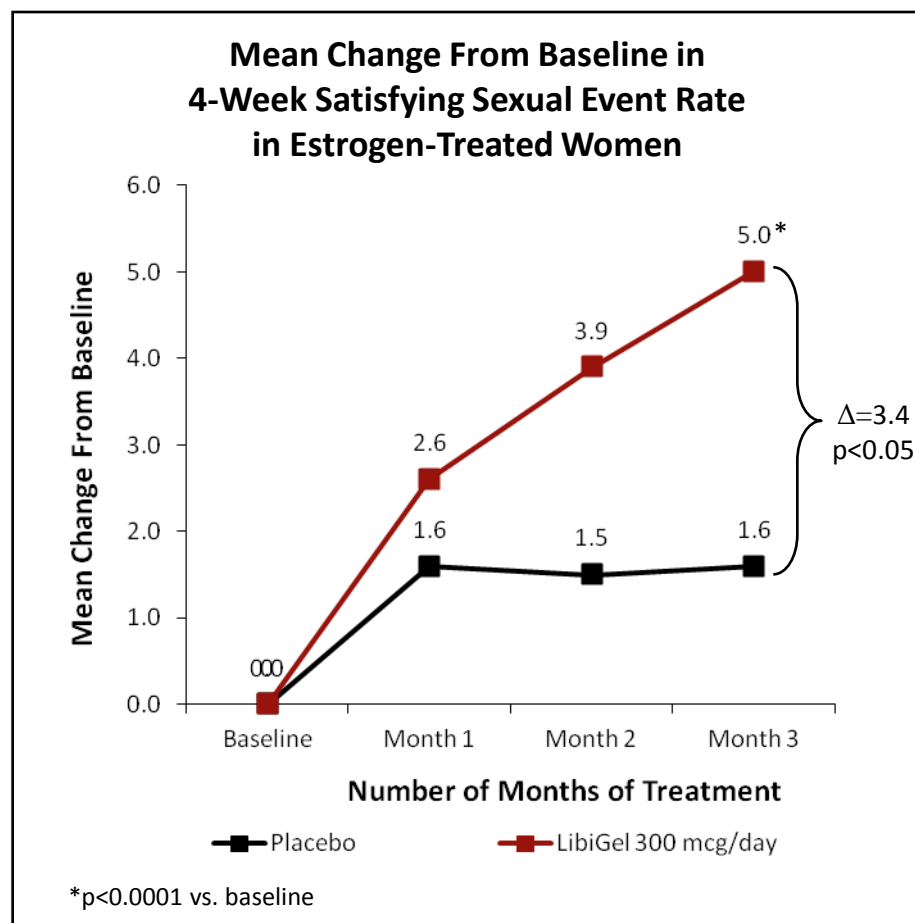
Physicians' favorable reaction can be viewed as a predictor of their willingness to prescribe based on clinical profile alone (without consideration of external factors).

Source: Results of Campbell Alliance primary research surveys/interviews with 101 physicians conducted in March 2010 to April 2010.

Differentiated Asset With Favorable Profile

LibiGel has shown to be an effective and safe agent for the treatment of HSDD.

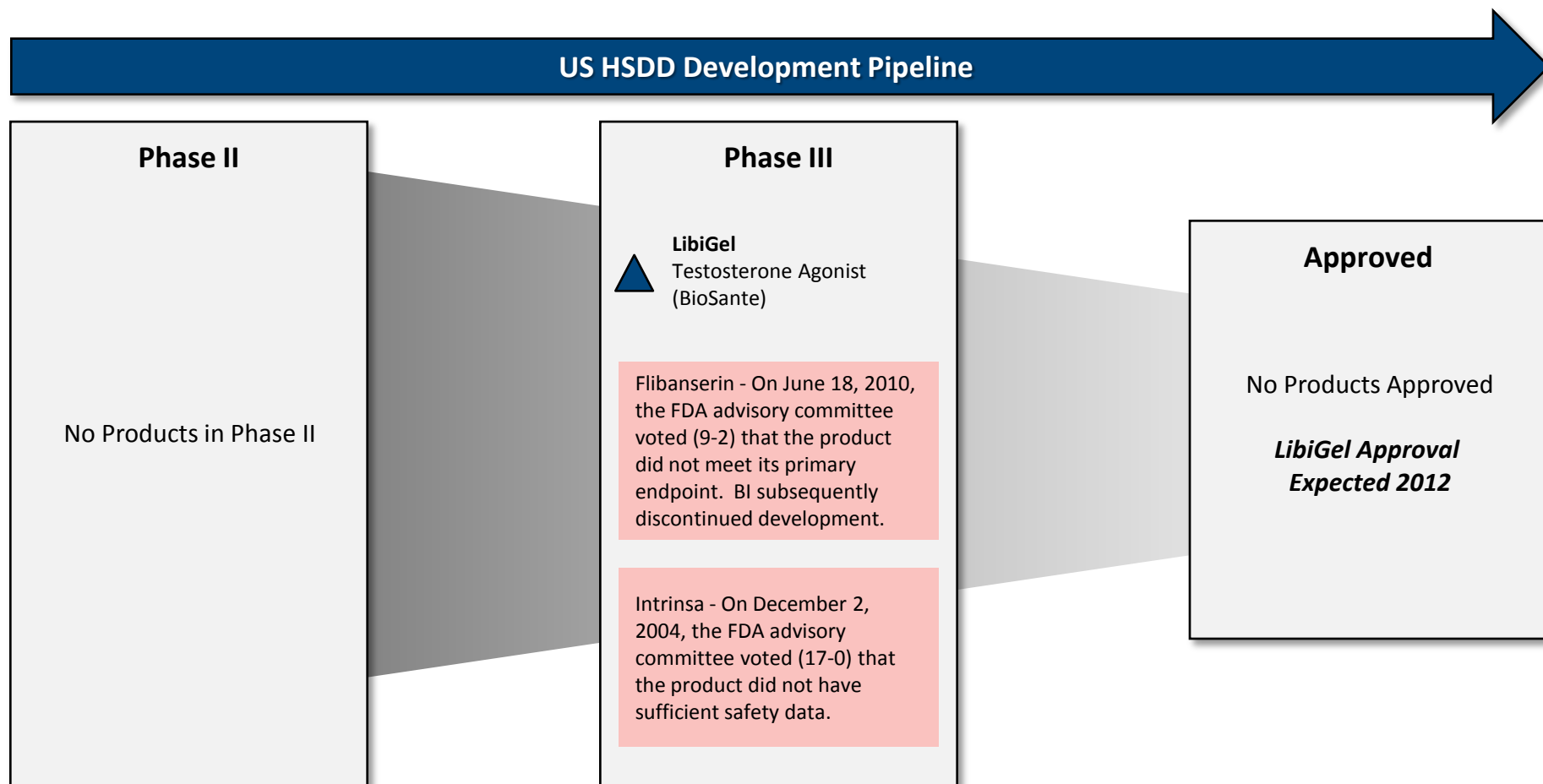
- There is currently *no clinically tested, FDA-approved pharmaceutical product for the treatment of FSD*, and LibiGel has the potential to become the *first-to-market product* for treating hypoactive sexual desire disorder (HSDD) in menopausal women.
- LibiGel successfully completed a phase II clinical trial showing *a 238% increase in the number of satisfying sexual events* vs. baseline ($p < 0.0001$) and statistically significantly better than placebo ($p < 0.05$) with *a safety profile similar to placebo*.
- Replicate phase III safety and efficacy trials currently are *recruiting under an SPA*.
- *Positive blinded ongoing results* (featuring lower than expected CV rates) have been demonstrated in a blinded phase III *long-term cardiovascular safety study*.



Source: Clinical studies sponsored by BioSante.

Anticipated to Be First to Market

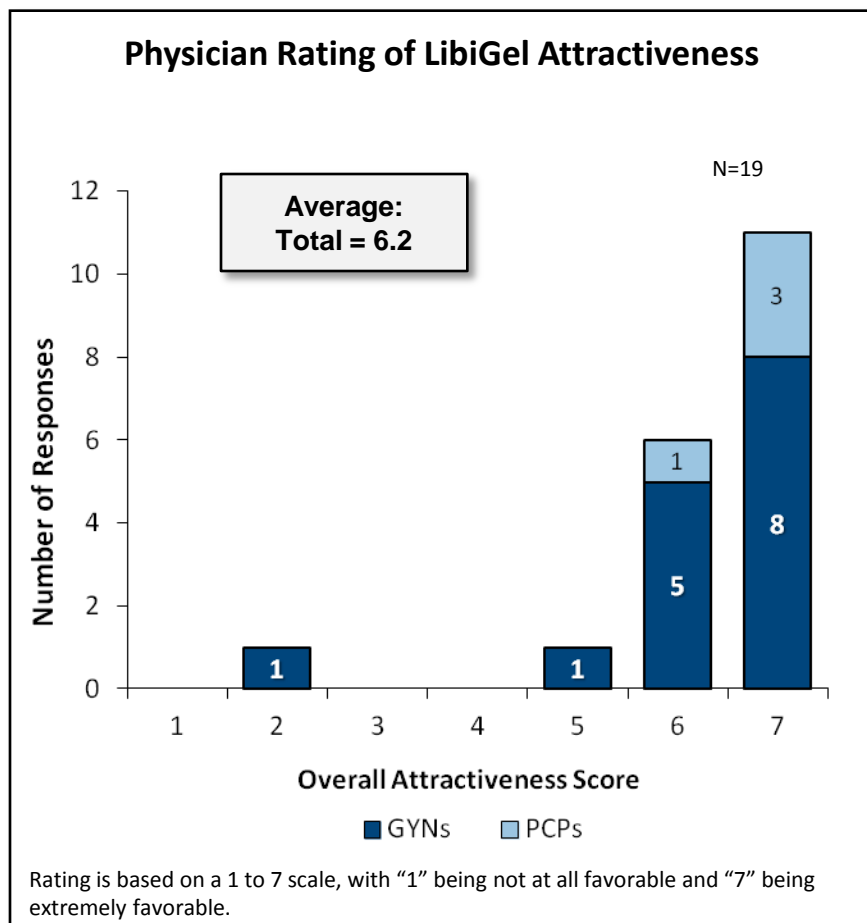
LibiGel is anticipated to be first-to-market product for the treatment of HSDD in the US.



Sources: Adis R&D Insight; PharmaProjects. Accessed June 2010.

Favorable Response From Prescribers

Almost all interviewed physicians rated LibiGel highly with the majority of physicians rating it a score of 7 out of 7.



- All but one interviewed physician rated LibiGel a **5 or higher**.
- Physicians noted several positive attributes of LibiGel:
 - Topical Mode of Administration
 - Efficacy
 - Female-Specific Dosing
 - Quick Absorption
 - Lack of Side Effects

*"This is answering **just what we need**, especially with the low side effects."*

– Gynecologist

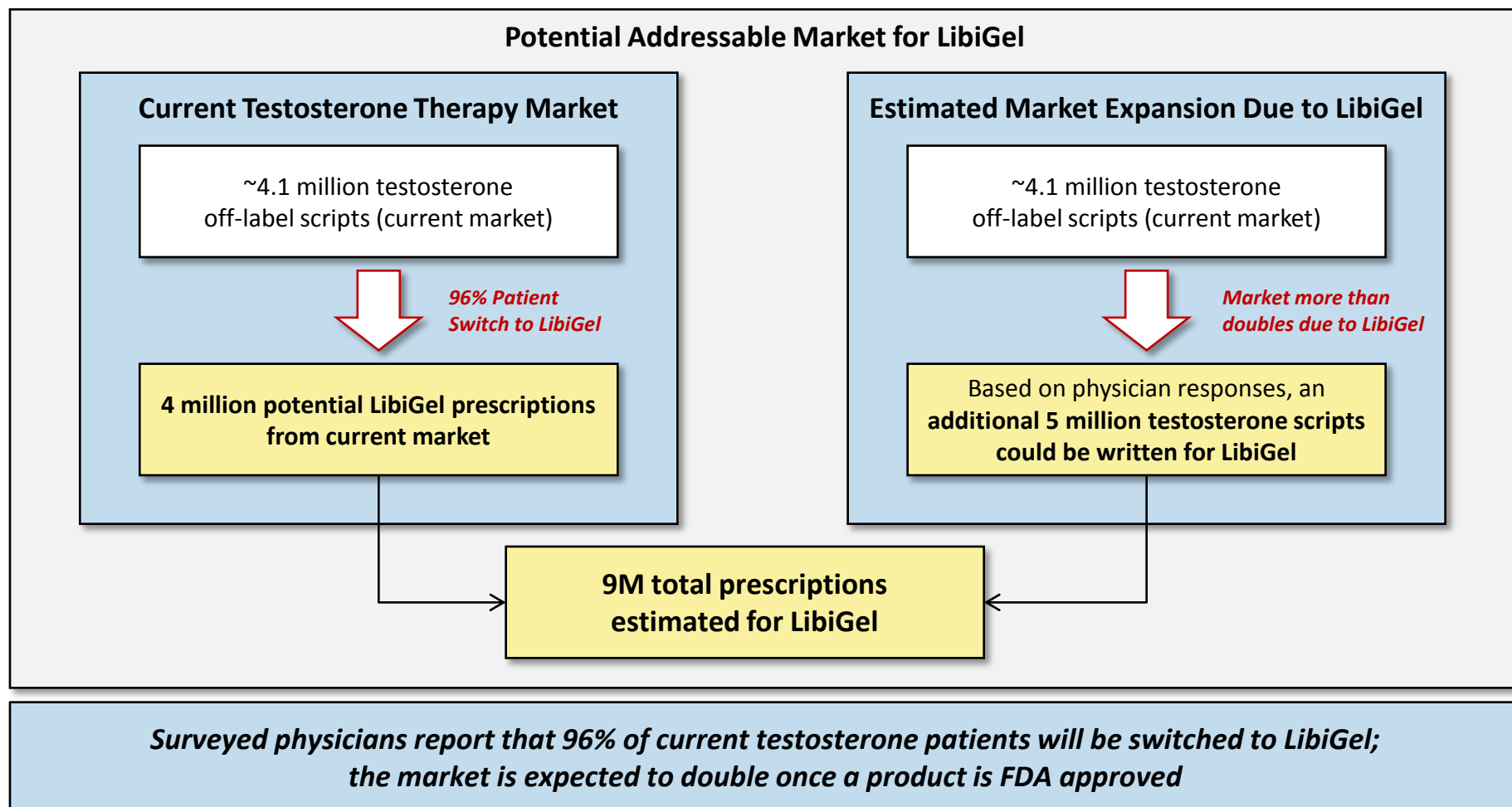
*"This is **what we've been waiting for**, a female dosing version of testosterone in a topical form... especially with some studies and pharmaceutical grade **consistency**."*

– Gynecologist

Source: Results of 20 interviews (15 OB-GYN, 5 PCP) conducted by Campbell Alliance in February and March 2010. Note: One physician did not respond to this question.

Revenue Opportunity—US Revenue Estimates for LibiGel

Due to favorable efficacy, safety, route of administration and FDA approval, LibiGel is *anticipated to dominate the current testosterone market* and *grow the FSD-treated population*—achieving blockbuster status.



LibiGel Clinical Development Status

Current phase III studies in progress for LibiGel include replicate efficacy and safety trials as well as a long-term cardiovascular safety study.

Phase III Replicate Efficacy and Safety Trials

- Two phase III trials already are underway *as specified by FDA's Special Protocol Assessment (SPA)*.
- Trials are designed to establish the efficacy and safety of LibiGel (testosterone gel) in the treatment of oophorectomized postmenopausal women with Hypoactive Sexual Desire Disorder (HSDD).
- The 24-week, randomized, double-blind, placebo-controlled trials include 500 subjects each, 250 per treatment group.
- LibiGel treatment group receives 300mcg/day dosing.

Phase III Safety Study

- A phase III randomized, double-blind, placebo-controlled multicenter cardiovascular safety study is well underway, *developed in consultation with and agreement from the FDA*.
- To date, over 2,750 postmenopausal women with elevated CV risk have been enrolled.
- CV event and rates have been very low to date in subjects who are at the higher end of the CV risk continuum for the intended treatment population. These blinded data demonstrate a lower-than-expected rate of serious CV events in the study thus far.
- NDA submission is planned after an average of 12 months of exposure.
- Subjects will be followed for four years after the initial 12 months post-NDA submission, potential approval, and launch.

Upon successful completion of the 24-week replicate efficacy trials and 12 months average exposure in a phase III CV safety study, an NDA for LibiGel will be submitted, and a product launch is anticipated in 2012.